PSJ3
Exhibit 183

From: Haddox, Dr. J. David
To: Rosen, Burt; Robert Twillman; June Dahl; 'Stewart B. Leavitt, MA, PhD' (stew202@comcast.net); Must, Alan
Sent: 1/11/2012 6:04:51 PM
Subject: PCF White Paper
Attachments: 2012-01-11-PCF White Paper.docx

All,

At long last, I offer my attempt at consolidating your excellent work and thoughts into what I hope reads a bit more consistently and opens the door for dialogue with CDC and other agencies.

I still need to work on inserting references, but I have the citations for most, if not all of them, including several that I added.

I tried to keep the three basic sections, but also tried to merge them into a more cohesive whole.

Edits, comments, criticisms are welcomed. I am happy to discuss another revision, following PCF members review.

Once we have settled on the work, we can all work to insert the references, which I have on a separate document for now.

If any of you feel I have taken too many liberties with your work, please let me know. Remember, however, that my choices were done only in an attempt to improve upon your already stellar work and no slights were intended.

Thank you for your patience and understanding.

Dave

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Pain, Analgesics, and Public Policy:

the need for accurate, complete, and timely data; thoughtful deliberation; and balanced actions

Preamble

In 2011, representatives from the US Centers for Disease Control and Prevention (CDC) and from the Pain Care Forum (CDC) engaged in a dialogue on a number of public health issues of mutual interest. CDC asked the PCF to share ideas and feedback and to suggest new opportunities for cooperation. CDC expressed particular interest in continued exchange of ideas on better utilization of Prescription Monitoring Programs (PMPs), approaches to controlling practitioners masquerading as legitimate pain management practices who dispense or prescribe opioid analgesics, benzodiazepines, and certain oral muscle relaxants without legitimate medical purpose (so-called "pill mills"), improved data collection on pain, and the potential of clinical guidelines in addressing these issues.

This paper represents a first step in proposing a collaborative path forward to address the concurrent problems of inappropriately-treated pain, criminal activity involving analgesics and other medicines, abuse of and addiction to opioid analgesics and illicit opioids, and overdoses in which opioid analgesics are present. In addition to addressing the issues specifically raised by CDC, thoughts on some basic issues of definitions and data presentation are presented.

Introduction

Conundrum: *n.* An intricate and difficult problem. (Merriam-Webster Online Dictionary)

United States public health authorities find themselves facing a conundrum as they seek to address these serious and intertwined public health issues. When viewed from the perspective of numbers alone, a significant proportion of Americans are directly or indirectly affected by one or more of these concurrent problems, as will be detailed below. The individual effects, however, are not revealed in statistics. The direct effects of inappropriately-treated (untreated, undertreated, and treated with incorrect medications, procedures, and techniques) pain can be as devastating and disabling for the individual as can be the consequences of abuse and addiction, up to and including death in both instances. The indirect effect of having a loved one or a family breadwinner impaired by pain and its consequences (eg, sleep deprivation, anxiety, depression, constricted social system, diminished or no ability to work) causes untold stress on families and relationships. Employers incur increased costs from pain suffered by their employees (eg, lost productivity due to presenteeism – presenting for work while impaired from pain, resulting in less output than normal – or absenteeism, increased stress on co-workers, increased Workers' Compensation costs). All of society pays for abuse, addiction, and diversion – economically in the form of higher costs in many ways (eg, public and private insurance fraud, pharmacy theft) and, as the headlines state frequently, with needless loss of life.

Because this public health conundrum has some many interrelated parts and players, the very real possibility exists for well-intentioned tactics aimed at ameliorating one aspect of the a problem can have significant unintended consequences that exacerbate another aspect of the same or an intertwined problem. Thus, policy makers and implementers are left struggling to achieve a delicate equilibrium in their attempts to formulate solutions. This paper will explore some important facets of the conundrum, summarizing the issues as they stand now and proposing considerations that may help the US achieve a balanced approach that is so essential for dealing with these public health concerns that affect the quality of life of tens of millions of our fellow citizens daily.

Chronic Pain

Chronic pain is experienced by 116 million adults in the United States, and is conservatively estimated to cost the American economy between $560 and $635 billion each year. Those numbers exceed both the prevalence of, and the costs associated with, cancer, diabetes, and heart disease *combined* (Institute of Medicine Report, 2011), suggesting that chronic pain represents the #1 public health problem in the United States.

Chronic pain can be disabling, with the IOM noting that people with severe pain miss an average of 5-6 more days of work per year than people with no pain (absenteeism). There are also those persons with chronic pain who, for economic and emotional reasons, continue to work, albeit at reduced capacity (presenteeism). Among people with various chronic pain conditions, the percentage who have experienced difficulty in basic functional areas (one or more of the following domains: movement, emotion, eyesight, hearing, cognition) in the past three months ranges from 14.3% for finger pain to 51.6% for low back pain (IOM Report, 2011).

The psychosocial toll is no less significant. Chronic pain is associated with significantly higher rates of depression, anxiety, helplessness, and anger among those who experience it and among those who care for them. People with chronic pain often feel powerless to help themselves, guilty over their lack of productivity and the costs of their care, and victimized by their pain. These emotional experiences affect their relationships with others, especially their close family members, for whom people with chronic pain may believe they are a burden. Unfortunately, these emotions and cognitions are shown to exacerbate the experience of pain, creating a vicious cycle. Further, studies demonstrate that the presence of unremitting pain contributes both directly (as a method of escaping pain) and indirectly (through its exacerbation of depression) to an elevated risk of suicide ideation and completion. (refs)

Because persistent pain is so complex, with prominent biological, emotional, cognitive, behavioral, social, and spiritual components, optimal treatment is often necessarily complex. Simple unimodal treatments such as surgery, nerve blocks, implantation of devices (nerve stimulators or drug-delivery devices), or medications rarely are sufficient to restore the person with chronic pain to a state of stable improvement in wellbeing. The IOM report recognizes this and calls for greater training in, and utilization of, multidisciplinary, multimodal, biopsychosocial treatments designed to address the complex needs of people with chronic pain. Healthcare delivery in the US currently is not well-suited to providing such integrated, coordinated approaches (eg, much reimbursement is piecemeal, with

procedures generating significantly more revenue per unit time than cognitive services; insurance policies with "carve outs" for particular types of services; availability of a full range of services throughout the US). Further, healthcare professionals are, for the most part, inadequately trained to even recognize, assess, or document the many aspects of the pain experience, much less intervene to address them. As a result, many rely on using larger and larger "doses" of the treatments they do provide (whether those treatments are medications, interventional pain procedures, psychotherapy, physical therapy, etc.). Application of progressively increasing amounts of any unimodal treatment for complex chronic pain conditions will likely result in poorer and poorer outcomes, as the untoward side effects of interventions accumulate, while the intended effects become static or even diminish. This is problematic for all interventions, but in the case of opioid analgesics, this approach may result in an increase in adverse events up to and including death and a greater supply in the community for diversion and abuse, which carries the risk of significant adverse effects with no potential for benefit. Until research and education advance to the point where most healthcare professionals understand and utilize a broad range of both pharmacological and non-pharmacological interventions and refer cases exceeding their expertise appropriately (which presumes an adequate supply and distribution of pain specialists that will accept such referrals), opioid analgesics will likely remain the predominant treatment for chronic pain and, therefore, as a nation, we must seek alternatives that minimize the risks associated with their use and optimize their benefit.

One major issue that complicates informed discussion is the lack of any ongoing survey of the incidence, prevalence, impact, access-to-care, and direct and indirect costs of acute and chronic pain in the US. PCF members are quite willing to engage CDC on how to periodically survey this problem, as a means of assessing the impact of various policies over time.

Nonmedical Use of Opioid Analgesics

In parallel with the unprecedented prevalence of chronic or persistent pain, is an equally serious unprecedented prevalence of nonmedical use of opioid analgesics and other medicines prescribed to persons for pain management. The National Survey on Drug Use and Health (NSDUH) defines "nonmedical use" (NMU) by an affirmative answer to the following: "Have you ever – even once – used any of these pain relievers that were not prescribed for you or that you took just for the experience or feeling it caused?" The 2010 NSDUH estimates 4.8% of Americans 12 years of age and older engaged in NMU of "prescription pain relievers" (most of which are opioid analgesics) in the past year. This number has been remarkably stable for much of the past decade, varying from a low of 4.7% in 2002 and 2004 to a high of 5.1% in 2006. Included in this number are an estimated 5.1 million persons who admitted to NMU of prescription pain relievers in the past month (referred to as "current" NMU) and 12.2 million with NMU of prescription pain relievers in the past year, of whom 1.9 million are estimated to meet DSM-IV-TR criteria for either "opioid abuse" or "opioid dependence" (addiction). This is a statistically significant increase from 1.6 million estimate in 2007. (SAMHSA)

The economic cost of NMU of licit opioid analgesics has not been well-researched. The US Department of Justice National Drug Intelligence Center estimated in 2011 that *illicit drug use*, which the federal government uses to describe both the use of illicit substances and NMU of licit medicines, in the United

States cost approximately $193 billion in 2007 (NDIC 2011). They did not estimate the proportion of this attributable to licit opioid analgesic NMU. Birnbaum (2006), analyzing data from 2001, estimated the cost of NMU of licit opioid analgesics to be $8.6 billion (about $11 billion in 2011 dollars). White, et al., (2005) estimated that overall healthcare costs alone for substance abusers were 8.3 – 8.7 times those of nonabusers. Finally, a 2011 analysis conducted for the state of Montana (Davis & Polzin, 2011) estimated the cost of abuse of licit medicines at $19.6 million; extrapolating proportionately from Montana's population of 989,000 to the United States population of 308.7 million gives an estimated national cost of $6.1 billion. Clearly, these estimates are widely divergent and a definitive answer is not readily apparent, but all of these estimates pale in comparison to the huge cost of chronic pain. Yet, for a society, the true costs, whatever the figures, are not mutually exclusive – they are additive.

On the surface, much more concerning are reports of a rapid increase in deaths related to improper use of prescription medications, in general, and opioids, in particular. In the final section of this paper, we will address some of the concerns about methodological issues related to these reports, but we will summarize here by citing a report from the US Centers for Disease Control and Prevention, issued in November, 2011: opioid pain relievers were involved in 14,800 prescription drug overdose deaths in 2008, nearly four times the *per capita* rate in 1999 (CDC, 2011). Coupled with the stable numbers of people engaging in nonmedical use of licit opioids, such a large increase is difficult to understand, although a variety of explanations certainly can be posited.

Addiction, in general, has been shown to have numerous adverse effects on people with the disorder. Although there are multiple definitions of addiction from various sources, they all recognize continued use of substances despite harm to the user as a hallmark of the disease (ASAM, 2011; FSMB, 2004; AAPM et al., 2001). This harm can take the form of economic loss (employment, benefits, real property, inheritance, etc.), social loss (friends, family), health loss (physical, mental), emotional (loss of sense of worth, guilt, shame) and spiritual loss (faith, hope). Despite these losses, a person with addiction continues to engage in compulsive use of the substance(s). The result can be utter devastation of the person's well-being and social network, the latter including not just the addicted individual, but those in their social sphere.

Approaches to controlling drug addiction in the United States largely have historically focused on controlling the supply of drugs of abuse. This strategy has produced modest success at best, and when applied broadly rather than to a specific target, may inadvertently reduce access to medications needed by people with pain while simply shifting the abuse problem to other substances. Such a result is becoming apparent now in Florida, where attempts to crack down on "pill mills" (*vide infra*) are giving rise to numerous reports from people with pain stating they find it very difficult to find physicians to prescribe and pharmacist to dispense their prescriptions. Supply-side solutions applied in the absence of concomitant demand-side solutions also likely produce a cyclical pattern with respect to which specific drugs of abuse are most popular. For instance, there are numerous reports that one result of reducing access to opioid analgesics through regulatory and law enforcement actions in one jurisdiction is an increase in use of heroin and importation of the desired opioid analgesics across State lines (eg, "The Flamingo Express" – a flight from Huntington, WV to Orlando, FL which was intended to increase commerce and tourism, but which became a favorite of drug "mules" ferrying drugs from pill mills in

Florida back to West Virginia, because of unchanged illicit demand in the face of a diminished local supply). Drug abuse control strategies are most likely to produce the desired effects without unintended consequences for legitimate users of opioids only when the supply-side strategies are precisely aimed at the appropriate targets and when accompanied by demand-side strategies such as effective primary, secondary and tertiary prevention, along with increased screening for problematic drug-taking behavior and access to efficacious addiction treatment.

Responding to the abuse-driven demand for licit opioids is an increase in supply. The NSDUH provides insight into the sources of medicines for abuse by asking persons who admit to NMU of prescription pain relievers about their sources of medicines for NMU. "Friends and relatives" (for free, by sale, or from theft) are the leading source, cited by 71% of the respondents. A little more than 17%, or one in six, state that they got the pain reliever most recently used nonmedically by prescription from one doctor, although the survey design doesn't shed any light on the nature of the interactions with doctors (legitimate medical need, feigned symptoms, complicit prescriber, etc.).

The Drug Enforcement Administration cites rogue Internet pharmacies as a significant source of licit opioids sold without legitimate medical need, though the NSDUH NMU respondents report it as a small source of prescription pain relievers for NMU (0.4%). The discrepancy is only an apparent one, however, as explained by DEA in a session at the 2005 American Pain Society annual meeting – the NSDUH figure is the percent of respondents, not the amount of drug trafficked by this means. As just two examples, in 2006, DEA found 34 rogue Internet pharmacies that had dispensed more than 98.5 million dosage units of hydrocodone products, while in 2008, a case was reported in which two Baltimore pharmacists were convicted of selling 9,936,075 units of hydrocodone online without legitimate medical purpose (Associated Press 2007, Madigan 2008).

"Pill mills" are illegal drug-dealing enterprises masquerading as pain management clinics, from which almost all "patients" receive controlled substances, often in large quantities without a medical exam or any documented reason for such treatment. These medications may be abused by the individual who receives them or sold on the illicit market. Law enforcement and public health authorities have called for increased efforts to eliminate these "operations" that have become major contributors to the current crisis of opioid diversion, abuse and overdose.

Pill Mills

Current Regulatory Efforts

Because medical practice is regulated at the state level, efforts to address the pill mill problem have been undertaken primarily by state legislatures and professional licensing boards. In this section, previous and ongoing efforts to deal with pill mills are reviewed, and some solutions to this challenge are proposed.

To date, five States (Florida, Louisiana, Ohio, Tennessee, and Texas) have passed statutes to enable State officials to close pill mills; Georgia is using existing statutory authority to create new to medical licensing board rules in order to strengthen its enforcement efforts., (see Regulatory References for citations on

all relevant statutes and regulations). In each case, authorities have established definitions for pain management clinics and instituted new standards for licensing and operation of those clinics. These new standards establish:

- Qualifications for *ownership* of pain management clinics
- Qualifications for *prescribers* working in pain management clinics
- Qualifications for a *medical director* for each clinic and the requirement that each clinic have a designated medical director
- Regulations allowing State agencies to inspect such clinics in the *absence* of a complaint
- Limitations on the *amount* of medication that can be dispensed by the clinic to an individual
- Required written policies and procedures that govern *operation* of a pain management clinic
- Required continuing *education* for clinic personnel
- Special *fees* for pain management clinics
- New *penalties* for violation of the standards

These efforts attempt to establish standards of practice that existing pill mills will not be able to meet; therefore, if they don't close on their own, they will be subject to administrative penalties that include revocation of the clinic's operating license. Because pill mills typically call themselves "pain clinics," it has been necessary to establish these higher standards for *all* pain management clinics in a given State, resulting in increased costs and regulatory burdens for the many legitimate pain practices.

Some policies enabling corporate ownership of medical practices of medicine allow non-physicians to own medical clinics; these policies may be created explicitly by statute in some States, while in others they evolve from case law. Perhaps the most important new standard is the requirement that "pain-management clinics" be owned by one or more physicians through either direct ownership by an individual or instruments such as Professional Associations or Professional Limited Liability Corporations.

Additionally, new pain-management clinic policies typically stipulate that clinic owners must not have been sanctioned in the past by State or federal authorities for violations related to controlled substances prescribing, and sometimes for other serious offenses. These requirements are in response to highly-publicized situations in Florida and elsewhere, in which some pill mills were owned by non-physicians with extensive criminal backgrounds, directly employing physicians and other prescribers. Such an arrangement exposes only the prescribers to administrative sanction, freeing the pill mill owners to simply replace sanctioned prescribers with others. The requirement that pain-management clinics be owned by physicians makes it possible for licensing boards to sanction physician owners and effectively close the pill mill.

Pain management clinics are consistently defined in the five states with existing pill mill laws and regulations as those in which the primary activity is the treatment of pain and in which the majority of patients receive prescriptions for federally-controlled substances, tramadol, and/or carisoprodol. Given that pill mills receive their income from prescribing and dispensing medications to a large number of customers and not from providing actual medical care, it has been presumed that a threshold of "50% plus one," or a simple majority, of "patients" within any month are prescribed federally- or state-controlled substances, or other specified drugs, should be sufficient to encompass all pill mills. A standard set at a higher percentage would risk allowing pill mills to dilute their patient panels by providing minimal medical care (flu vaccinations, school sports physicals, etc.) to a relatively small number of patients.

Unfortunately, there have been reports (some entered into the public hearing record for the Ohio medical board rules adopted in July 2011) of physicians abruptly ceasing to prescribe controlled substances to legitimate patients as a means of ensuring that their practices do not exceed the prescribing/dispensing threshold specified in the statute(s). This unintended consequence has resulted in these patients suffering acute opioid withdrawal and needing to find new prescribers; the physicians have not been sanctioned for patient abandonment.

Also impacting a lesser number of practices, but of national importance is that, to date, the statutory language has the possibility of negatively impacting those legitimate practices that would otherwise not meet the prescribing/dispensing threshold, but for participating as an investigative site in an FDA-approved clinical trial involving any of the covered drug substances. Anecdotal reports have suggested the additional presumed scrutiny and extra requirements are dissuading some practices from participating in these needed activities.

The five States with pill mill policies have specified the need for pain-management clinics to designate a physician as the medical director of the clinic, with oversight responsibility for the clinic's practices. These physicians generally are required to be board certified, with subspecialty certification in pain medicine or in hospice and palliative care, or to demonstrate adequate experience in a pain management clinic plus substantial continuing education requirements. Typically this standard will not be met by pill mills, which tend to employ older physicians who may have been unable to find employment elsewhere, and who are less likely to hold primary or subspecialty certification by a board recognized in the Statute.

Key among these new standards for pain-management clinics is the stipulation that regulatory agencies do not require a complaint as the basis to inspect pain-management clinics. This is likely to be the single most effective strategy to identify and sanction pill mills. Most medical licensing board and related agencies require that a formal complaint be filed; the board then determines if the complaint is serious enough to warrant opening a full investigation of the clinic. In the case of "pill mills," the only likely source of complaints is fellow medical professionals, as it is unlikely that "patients" will complain and the typical cash-only basis of operation for the pill mills eliminates insurance companies as potential sources of complaints. Historically, other medical professionals and law enforcement agencies have been reluctant to complain for a variety of reasons. Allowing inspections with few limitations, or even

requiring them on a regular basis, permits regulators to examine the practices within a clinic and thus readily identify those who fail to meet even the most basic of standards for controlled substance prescribing: that it is done for a legitimate medical purpose and in the usual course of professional practice.

Finally, statutes in Florida and Ohio have eliminated (Florida) or restricted to a 72-hour supply (Ohio) the dispensing of controlled substances from medical practices. Most pill mills, in jurisdictions where it is allowed, dispense medications directly, to increase profit and to avoid scrutiny of their practices by pharmacists who would otherwise dispense the medicines from a prescription. To further increase their profit, they also require payment for the both the "office visit." Direct dispensing of controlled substances by physicians was so prevalent in Florida that, in the first 6 months of 2010, it was estimated that dispensing physicians in Florida purchased 41.3 million dosage units of oxycodone, compared to 4.8 million dosage units purchased by dispensing physicians in the remaining 49 states (Gallagher, 2011; it should be noted that the #2 state in terms of physician purchases of oxycodone was Ohio, where physicians purchased just over 1 million dosage units). Further, according to a report prepared by DEA using the ARCOS data, in 2010, 98 of the nation's top 100 dispensing physician purchasers of oxycodone had business addresses in Florida (Scott 2011). By eliminating or severely curtailing physician dispensing, states hope to insert one more check into the process, in the form of a pharmacist who must fill prescriptions from the pill mill. Unfortunately, the entrepreneurial nature of pill mill owners has led some to simply open pharmacies in spaces adjacent to their pill mills, leading some cities and counties to develop zoning ordinances specifying minimum distances between medical clinics and pharmacies.

In general, efforts in Louisiana, Texas, and Florida, have been successful in identifying and closing a large number of pill mills in the few months they have been operative. Unfortunately, these new policies have had unintended consequences. In Florida, some authentic patients are having difficulty getting pharmacies to fill legitimate prescriptions for controlled substances. The type of ordinance governing physical proximity of pain-management clinics and pharmacies, of course, can have negative consequences for patients with chronic pain who lawfully avail themselves of the services of a pharmacy that is conveniently located in the vicinity to their prescriber. As noted above, some Ohio physicians abruptly dropped patients to ensure that their practices did not qualify as pain clinics, at the cost of putting those patients through acute opioid withdrawal. Other patients from Ohio have noted that they are now being required to see their physician monthly instead of quarterly, because the physicians are confused and fearful about the consequences of inadvertently failing to meet the new standards of practice. And still other physicians have told us that they are moving out of these states or leaving pain management practice altogether because of the burdens of complying with these increased regulations, despite the fact that they have been in practice for many years without ever being the subject of a complaint. Clearly, this is an instance in which policy makers need to strive for balance, creating policies that allow authorities to quickly and easily shutter pill mills while not placing undue burdens on the vast majority of legitimate pain clinics and the patients they serve.

Considerations for Future Action

In devising public policy solutions to the problem of pill mills, it is necessary to ask what the appropriate "target" of those solutions should be. Can we craft narrow policy solutions that enable us to identify and close pill mills – selectively, efficiently, and at minimal cost? Or do we need to continue to develop solutions that affect all pain clinics, the vast majority of which are legitimate and are dedicated to providing the best care available to a large number of people with chronic pain? Is it right to establish higher standards for pain-management clinics compared to other medical practices, simply because a small number of rogue pill mill operators have chosen to call themselves "pain clinics"?

In general, approaches that are specific to pill mills should be pursued, making it possible for regulators to identify and close them with ease. Targeting pain-management clinics as a group is risky, as forcing them to take on extensive and sometimes onerous regulatory and financial burdens may lead some to alter the makeup of their patient panels, move out of state, or simply close, none of which guarantees that pill mills will be affected and all of which have the potential to adversely affect patients with chronic pain who have legitimate medical need for and are clinically appropriate for drug substances covered by these statutes, regulations, and ordinances. This would be a tragic result for a medical system that already is marked by a paucity of high-quality pain care for the estimated 116 million American adults with chronic pain.

An alternative is to design solid policies that apply to all medical practices in a given State. Such a strategy allows regulators, especially medical licensing boards, to safeguard the public health on a broad basis, while simultaneously permitting them to effectively target pill mills. Among suggested areas for policy development are the following:

- Corporate practice of medicine issues—who should qualify to own a medical practice? Some that believe medical practices should be owned only by physicians, either solely or as part of a legal entity composed solely of physicians.
- Establishment of a medical director position in all clinics, with specific qualifications for holding such a position, such as board or subspecialty certification, or adequate work experience with appropriate continuing education.
- Clarification of licensing board policies regarding what behaviors evidence a legitimate medical purpose and the usual course of professional practice.
- Policies allowing licensing boards and other regulatory oversight agencies to inspect clinics without notice and in the absence of a complaint
- Substantial limitations on the direct dispensing of controlled substances by any healthcare practitioner other than a pharmacist. Allowing a non-pharmacist practitioner to dispense limited quantities of controlled substances for specific situations may be prudent.
- Requirements that dispensing practitioners report the same information as a pharmacy would to the State's prescription monitoring program.

- Continued dialogue among and training of regulators (such as boards of medical examiners) on appropriate criteria for administrative sanction (eg, Are there single instances that would demonstrate a practitioner represents a threat to a patient's or society's wellbeing? What types of patterns demonstrate the same?)

- Encouragement of more open and direct relationships between law enforcement agencies and licensing boards, so that law enforcement does not hesitate to consult licensing boards about the propriety of practitioners' behavior, and licensing boards do not hesitate to refer cases to law enforcement for investigation if they determine that the behavior crosses the line between medical malpractice and criminal behavior.

Through policy changes such as these, it should be possible to craft statutes and regulations that carry out the intended purpose of eliminating pill mills, while simultaneously improving the provision of all types of medical care and avoiding the kinds of unintended consequences already seen in states that have adopted "pill mill" statutes and regulations in the past few years.

Prescription Monitoring Programs

Prescription monitoring programs are one of the tools states use to address the diversion and abuse of controlled substances. They are commonly referred to as PMPs or, alternatively, as PDMPs (prescription drug monitoring programs). PMPs collect data about controlled substances and other "drugs of concern" that are dispensed in a state, compile and review the data, and almost all make the data available to regulatory and law enforcement agencies and/or clinicians. Although these programs were originally designed as law enforcement tools, they have gradually evolved so they now have the potential to have a significant positive impact on the public health, in particular on the management of pain.

The National Alliance for Model State Drug Laws (NAMSDL), briefly outlined the multiple purposes PMPs may serve: "(1) support access to legitimate medical use of controlled substances, (2) help identify and deter or prevent drug abuse and diversion, (3) facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs, (4) help inform public health initiatives through online use and abuse trends, and (5) help educate individuals about PMPs and the use, abuse, diversion of and addiction to prescription drugs."(NAMSDL 2009, DEA 2012)

Thus, PMPs can provide health care professionals with critical information about a patient's drug treatment history and alert them to persons who are obtaining prescriptions from multiple clinicians, obtaining drugs from multiple pharmacies, or using multiple drugs that have the potential to be abused. PMPs may allow identification of physicians who prescribe unusual quantities of drugs or predominantly prescribe combinations of drugs that are sought by abusers (eg, hydrocodone/APAP, alprazolam, and carisoprodol); they may identify the recipients of such quantities or combinations; they may provide patient-specific information upon the request of a prescriber or pharmacist; and some offer educational programs about the nature and extent of the problem and medical treatment options for drug abusers. Giving individual health care professionals access to data about their individual patients allows them to evaluate their patients' use of controlled substances and other drugs of concern. The White House Office of National Drug Control Policy and the Centers for Disease Control have endorsed PMPs as an important mechanism for helping prescribers and pharmacists identify high-risk patients. (ONDCP 2011, Paulozzi 2011)

There are as yet no published studies to document the impact of these programs on the diversion and abuse of opioid analgesics, but there are reports of other benefits and indications that utilization of PMP databases can improve the quality of pain care. However, other potentially important sources of diversion are generally not captured by PMPs, including controlled substances dispensed within healthcare facilities (eg, hospitals, long-term care facilities, hospices), illicit sales from rogue internet pharmacies; mail-order sales; direct dispensing, where allowed, by a practitioner to a person without writing a prescription for dispensing from a pharmacy (with or without legitimate medical purpose), and losses in the supply chain, although the latter losses (in-transit, warehouse, pharmacy theft) are ostensibly captured in the database maintained by the federal DEA via Form DEA 106 reporting

requirements. The magnitude of diversion via these and other methods is unknown and PMPs often do not have timely access to federal data to construct a complete picture of diversion within their State. Further, even well-operated PMPs will not have data on the amount of drug diverted by various criminal activities.

History

The first PMP, established in California in 1939, required physicians to write prescription orders for Schedule II controlled substances on triplicate prescription blanks; one copy stayed with the prescriber, one with the dispensing pharmacy, and the third went to a State agency. The utility of this paper-based system for healthcare or law enforcement purposes was obviously limited. Further, the prescribers were required to purchase the triplicate forms from the State, which would only mail a limited quantity at one time, creating access problems for those patients seen by prescribers whose practice demand exceeded the timely supply of the prescription forms.

Between 1943 and 1988, other States adopted PMPs that required the use of triplicates, duplicates or single-copy forms, also purchased from a government agency. The year after a triplicate program was introduced in the State of Texas in 1982, there was a dramatic decrease in the prescribing of Schedule II opioids, for which the government-issued forms were required, and a commensurate increase in the prescribing of Schedule III opioid combination drugs, which could be dispensed via a traditional prescription form. A dramatic decrease (33% in one quarter) in prescribing of benzodiazepines (Schedule IV) occurred when New York added them to the other drugs (Schedule II) requiring triplicate prescription forms in 1989. The decrease was accompanied by an increase in the prescribing of older sedative hypnotics with significant potential adverse effects (eg, meprobamate, 12.5% increase; ethchlorvynol, 29% increase; chloral hydrate, 136% increase), despite flat or slightly decreasing national trends for these non-benzodiazepines. Clinicians claimed these changes in prescribing were due to fears of government scrutiny, while regulators claimed that the decrease indicated a drop in inappropriate prescribing. (Weintraub 1991)

When pharmacies began to use computers to send information to third-party payers, states moved from paper-based programs to electronic tracking of dispensed drugs. Oklahoma implemented the first electronic PMP in 1991; by 1994, 16 states had established such programs. As of January 2012, 38 states have operational PMPs (Alliance 2012). The District of Columbia and the ten remaining states have enacted legislation to establish PMPs, but their programs are not yet operational. PMP legislation is pending or under consideration in New Hampshire and Missouri, respectively. Although the common goal of these programs is to reduce prescription drug diversion and abuse, there is wide variation in program design, objectives, and operation. They also differ in where they reside within a state's executive branch structure; while PMPs were initially housed in law enforcement agencies, more recent programs are administered by a state's department of health or board of pharmacy. The DEA is not directly involved in the administration of any PMP, although it is a strong proponent of these programs. (DEA 2012)

Although Pennsylvania tracks only CIIs, all other state PMPs track Schedule II-IV or Schedule II-V controlled substances. Some also require that the dispensing of other drugs of concern such as tramadol and carisoprodol be reported. DEA has issued a final rule to place carisoprodol in Schedule IV of the Controlled Substances Act in January 2012. Prescribers in Texas must use a special government issued prescription form for Schedule II controlled substances. New York requires all prescription orders to be written on bar-coded serialized prescription forms, but only information about controlled substances is reported the State's Bureau of Narcotic Enforcement. New York does, however, require that dispensing practitioners also report to their dispensing of controlled substances to the PMP. (New York 2007)

Data Sharing

With the growth in the number of PMPs has come recognition that there is a need for information sharing among states because as one sage commented "no state is an island."(Beshear 2011) In many instances, clinicians in one State may provide care and prescribe medications for patients who live in another State. This may arise from proximity (eg, the nearest physician who treats a particular issue is across an interstate border), from temporary duty assignments (eg, temporarily-relocated utility workers assisting local utilities with electrical power restoration following a hurricane), or periodic relocation (eg, "snowbirds" from New England who spend part of the year in the Southern US). Without the ability to share PMP data across state lines, there concerns about persons shifting their illegal activities to another state and, equally as important, concerns about access to appropriate care if a practitioner in one State is unable to efficiently review dispensing information on a particular patient that occurred in another State. Multi-state cooperation seems essential if these programs are to accomplish their goals. A national advisory panel convened by The Council of State Governments' National Center for Interstate Compacts developed recommendations for an Interstate Compact on Prescription Drug Monitoring. Its purpose is to provide a framework for state administered prescription drug monitoring programs to securely share data to improve public health and safety. This model requires funding from the States to sustain the Compact. In light of the current fiscal status of most states, this model has not been widely accepted and only Maine has passed the necessary legislation to implement its participation.

In July 2011, the National Association of Boards of Pharmacy launched PMP Interconnect, a highly secure communications exchange platform that facilities the transmission of PMP data across state lines while ensuring that each State's data-access rules are enforced. Costs will be absorbed by the organization; NABP has made a commitment that there will be no cost to participating States for at least five years.(NAPB 2012a) Three states (Ohio, Indiana and Virginia) are currently sharing data through this system. In the first 120 days of operation, 62,755 interstate requests were processed, with an average of 15 seconds wait for a consolidated multi-state report. (NABP 2012b) NABP anticipates that by the end of 2012, 30 states will use NABP Interconnect to share data.

Funding

Funding for PMPs comes primarily from state and federal grants. The Department of Justice (DOJ) administers a competitive grants program, the Harold Rogers Prescription Drug Monitoring Program, which provides funds for creation or improvement of existing PMPs. Its purpose is to enhance the capacity of law enforcement and public health officials to collect and analyze PMP data through a centralized database administered by an authorized state agency. The Harold Rogers Program provides three types of grants: planning, implementation, and enhancement. Funding for FY 2011 is approximately $5.6 million. The DOJ-funded efforts emphasize the law enforcement rather than the public health aspects of prescription drug diversion and abuse. One concern of these grants is that the language for the 2011 grant awards "Priority Consideration" to applicants who propose to implement information sharing with other state PDMPs within the grant period using the prescription monitoring information exchange (PMIX) specifications. There are currently no states that are utilizing this system to share data and, while the NABP system is available and operational, it is unclear whether the use of this program will also qualify for Harold Rogers grants.

The National All Schedules Prescription Electronic Reporting Act (NASPER) authorized a system of federally funded, inter-operative, state-based prescription drug-monitoring programs and the promise of an important tool for physicians to use to address patient abuse and diversion of pain medications. NASPER is administered through the Department of Health and Human Services; its purpose is to foster PMPs that would meet consistent criteria and have the capacity for the interstate exchange of information. Although signed into law in 2005, it received no funding until FYs 2009 and 2010 when $2 million was appropriated.

The National Association of State Controlled Substances Authorities (NASCSA) has provided additional funding for state PMPs through the Prescription Drug Monitoring Program (PDMP) Grant Program. Funds are intended to support the operation, expansion and awareness of appropriately-designed state prescription drug monitoring programs and can be applied for by the state PMP administrator. A Special Projects Committee is responsible for evaluating the proposals and making recommendations to the Executive Committee which makes the final award decisions.

There is great concern about the affordability of these programs in the current economic climate. The Associated Press reported on November 17, 2011 that budget cuts threaten to make the CA PMP obsolete. No one will be left to run the program starting next year unless funding is found. The program's annual cost is $1million.

Impact

While well-designed PMPs are intuitively a good idea, there are no studies that provide definitive evidence that they reduce the diversion of covered drugs, abuse, or overdose deaths involving opioid analgesics. There are also no definitive studies that show an effect, adverse or beneficial, on access to appropriate pain care. The possible impact of PMPs on the use of stimulants for the treatment of attention deficit disorder has not been investigated. Two studies showed that PMPs reduce investigation time, that is, they improve the timeliness and cost per hour of law enforcement and regulatory investigations. This has been viewed as a positive outcome.

Simeone and Holland examined the effects of PMPs on the supply and abuse of prescription drugs. They concluded that "states that are proactive in their approach to regulation are more effective in reducing the per capita supply of prescription pain medicines and stimulants than are those which are reactive in their approach to regulation." Interestingly, they reported that the probability of pain reliever abuse was actually higher in states that have PMPs than in states that do not. Yet they concluded that "their analysis demonstrates that in the absence of such programs the probability of abuse would be higher still." Wang and Christo reported that PMPs not only reduce the time and effort for law enforcement agencies to conduct investigations, but also cut the supply of prescription medications. A concern about any action that reduces the supply of prescription medicines is the ability to demonstrate that the reduced supply affected only those persons involved in improper use of the medicines, which have no effect on, or even improving supply of, the same medicines for patients with legitimate medical need. Investigators who analyzed US mortality data by state and by year for the period 1999-2006, concluded that PMPs "were not significantly associated with lower rates of drug overdose or opioid mortality or lower rates of consumption of opioids."(Paulozzi 2011) PMPs had minimal effect on overall consumption of opioids. States with PMPs dispensed significantly greater amounts of hydrocodone and non-significantly lower amounts of CII opioids. The increase in overdose mortality rates and use of prescription opioid drugs during 1999-2005 were significantly lower in the three States with PMPs (CA, NY and TX) that required the use of special prescription forms in the study timeframe. A small study used the Ohio PMP database to examine the impact of that PMP on clinical management of emergency department patients with painful conditions. After review of the PMP data, providers changed their clinical management in 41% of the cases; the majority of those (61%) resulted in fewer or no opioid medications prescribed than originally planned, whereas 39% resulted in more medications than previously planned. The authors point out that it may be more difficult to use these data in planning for treatment of persons with chronic noncancer pain.

Considerations for Future Action

NAMSDL emphasizes that PMPs exist to support legitimate medical use of controlled substances while limiting drug diversion and abuse. Well-designed, efficient, easy-to-access (eg, integrated into electronic health records), comprehensive PMPs that allowed interstate access to data could obviate the need for Medicare/Medicaid lock-in programs, Risk Evaluation and Mitigation Strategies and other federal, state, or private (insurance program) mandates that have the potential to adversely affect the quality of care. There is a pressing need for carefully-designed studies to document the impact of these programs so that recommendations for change can be based on evidence of best practices.

Until such time as clear, uncontested, scientific evidence to provide guidance about how NAMSDL's objective will be achieved exists, the following elements, many of which have been implemented in some PMPs, seem obvious for a PMP to be optimally beneficial:

1) Recognize the principle of balance between control of substances to prevent harm to the individual and society, while at the same time, ensuring access to those substances for legitimate medical and scientific purposes.

2) Avoid the use of government-issued multiple-copy, or single-copy serialized, prescription forms.

3) House the program in a State agency that primarily deals with health care, rather than in a agency primarily concerned with law enforcement.

4) Collect data on all controlled substances in Schedules II-V or II-V with flexibility to include other, non-scheduled, drugs of concern.

5) Ensure accurate, comprehensive data are collected about the prescriber (name, DEA registration number, etc.), the drug dispensed (name, strength, quantity, directions for use, presence and number of refills, etc.), the intended recipient (full name, DOB, SSN or other unique identifying number, etc.), and the dispenser.

6) Require pharmacies to submit data to the PMP at least weekly, while working toward a uniform standard of daily or real-time submitting (eg, the way credit cards used to pay for co-pays or the prescription are adjudicated at the point of dispensing).

7) Establish penalties for failure to comply with submission and data quality requirements.

8) Establish advisory committees, comprising a broad array of stakeholder types, to monitor the operation of the program, suggest improvements, and assure the accuracy and security of the database.

9) Permit prescribers and dispensers real time access to information in the database about current or prospective patients.

10) Provide mechanisms for reporting errors and/or security breaches.

11) Do not require prescribers or dispensers to access the database prior to every instance of prescribing or dispensing controlled substances until such time as the burden on the healthcare system is minimal.

12) Require the implementation of an educational program to teach potential database users about accessing and utilizing data from the PMP.

13) Require aggregate, de-identified information be available to public or private entities for research, statistical, or educational purposes.

14) Protect patient, prescriber, and dispenser confidentiality to the greatest extent possible.

15) Allow law enforcement agencies access to the data when appropriate criteria are met, such as when probable cause exists from an ongoing investigation of possible fraud or diversion of a prescriber, dispenser, or recipient of dispensed drug.

16) Require periodic reporting on the impact of the PMP on:

a. patients with legitimate medical need for the covered medicines,

b. the prevalence diversion of covered medicines, and

c. the prevalence of abuse

Data Presentation and Definition Needs

The public interest will best be served by rational, objective, accurate collection and presentation of data, using clear, consensus-based terminology and avoidance of emotionally-charged rhetoric.

Research and communication on the problems addressed in the paper are hampered by inconsistency in the use and meaning of terminology. Several examples are illustrative:

- The operational definition of nonmedical use differs significantly between the NSDUH and the Drug Abuse Warning Network, both of which are supervised by the same federal agency. In NSDUH, the threshold is the answer to the NMU question discussed earlier, while DAWN uses an unclear aggregation of certain types of cases, from a hierarchical ranking based on the motivation for a drug-related visit to an emergency department. (SAMHSA 2006a)

- The term "misuse," as applied to licit medicines, is defined differently by FDA, NIDA, and SAMHSA, three agencies within the US Department of Health and Human Services.(Volkow 2010, FDA 2010, SAMHSA 2006b)

- The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) does not have a diagnostic label for nonmedical use of a licit medicine until recurrent (episodic) or continued substance exposure results in a maladaptive pattern of use leading to clinically-significant distress. Thus, initiates of NMU, while clearly engaging in dangerous behavior are, according to the APA, diagnostic orphans, making statistical analysis non-uniform and reimbursement for interventions unlikely.

- The use of terms to describe opioid analgesics to the general public by representatives of government or academic institutions such as "narcotics" or "pain killers" inject emotion and confusion into what should be an objective characterization of a public health problem, a solution to which, involves enlisting the general public's understanding and support.

- Characterizing a death in which opioid analgesics were detected as an "opioid death" is, in many instances, an incomplete description of the contributing cause(s) of death and does not lend to rational interventions.

- Even a term as intuitively obvious as "prescription pain reliever" or "prescription opioid analgesic" can be misleading, since many of these medicines, while required to be provided to a

person only upon the order of an authorized healthcare professional, are in fact, not issued by prescription (eg, patients in hospitals, some hospices, long-term care facilities, prisons; persons who obtain them unlawfully).

To safeguard the public while meeting the needs of patients with pain, a balanced understanding of the issues, considering both risks and benefits, is needed to arrive at solutions that are equitable and just for all members of society. Following are some observations and suggestions for working toward appropriate balance in the dialog surrounding opioid analgesics.

The National Center for Injury Prevention and Control (NCIPC) of CDC has been at the forefront of gathering, analyzing, and disseminating important information on the impact of increasing opioid analgesic prescribing in the United States. Certainly, this has been a vital service in the interest of public health, and legislators, policy makers, the medical community, and the public looks to the NCIPC/CDC for accurate and unbiased information.

Several recent documents distributed by NCIPC/CDC on November 1, 2011 indirectly suggest several areas in which a more balanced dialog on opioid analgesics might be achieved [Paulozzi et al. 2011; Policy Impact 2011; Vital Signs 2011]. A number of important trends are emphasized in those papers:

- Opioid analgesics have been increasingly prescribed during the past decade for many types of pain conditions, and a special concern has been the prescribing of these medications for chronic pain of various etiologies unrelated to cancer.

- There also have been alarming increases in the incidence of drug overdoses and deaths associated with prescription opioid analgesics.

Language makes a difference in how issues are perceived. Taking the CDC information referenced above can be instructive. The MMWR referenced above is entitled: "Vital Signs: Overdoses of Prescription Opioid Pain Relievers — United States, 1999–2008." In the boxed summary, the first statement is "Overdose deaths involving opioid pain relievers (OPR), also known as opioid analgesics, have increased and now exceed deaths involving heroin and cocaine combined." Is it useful to characterize an overdose death in which an opioid analgesic was involved (often along with other substances, based on prior research reports) as an "Overdose of (a) Prescription Opioid Pain Reliever"? The report doesn't elaborate on the types and frequencies of other drug substances, licit and illicit, found in the decedents, nor does it discuss how these may have contributed to or even caused the death.

Clearly, in the interests of public health there is a need to control and ameliorate problems surrounding the improper use of opioid analgesics. At the same time, and also in the best interests of the community at large, access to these vital and essential medications must be preserved for persons in pain who need them daily for comfort, functionality, and a reasonable quality of life. While it is duly recognized that opioids are not the only therapies for pain control, or even the best or most appropriate

treatment for many patients, they are a vital and essential component of currently accepted best medical practice.

The MMWR also reports:

- "During 1999–2008, overdose death rates, sales, and substance abuse treatment admissions related to OPR increased in parallel."

The use of data showing sharp increases in admissions to substance abuse treatment programs involving opioid analgesics to support an argument of too much availability comes with some significant caveats. It is unclear, for example, what proportion of those admissions was for opioid-induced problems, compared with those associated with opioids plus alcohol, marijuana, or other drugs. Using these data to confirm an increase in prevalence assumes treatment-seeking remains at a constant proportion of those needed treatment, yet SBIRT, etc. is promoting awareness and intervention. Therefore, the data could also be viewed in a positive light, since they might represent an increased recognition of substance use problems and their consequences, as well as a greater willingness of persons in need to seek treatment.

When using death data, there are reporting biases that must be considered. There is lack of uniformity of autopsy performance standards, deciding when to perform one, how they are reported, consideration of the development of tolerance to the sedative and respiratory-depressant effects of opioids taken medically or nonmedically on a regular basis, scope and type of toxicology studies, and training of coroners and medical examiners. In some jurisdictions, coroners are still elected officials and forensic training experience, or even possessing an MD or DO degree, are not requirements for office.

Finally, the CDC and other government agencies have characterized overdose deaths and other problems relating to prescription opioids as an "epidemic." This term is commonly defined as a disease or condition affecting a disproportionately large number of individuals within a population.

While there may be a need for provocative language that draws public attention to the very serious opioid-related problems discussed in this paper, it is unclear why these particular problems are considered to be of epidemic proportions. For example, in balance, it might be questioned why 14,800 opioid-related deaths are an epidemic, whereas, more than 24,000 alcohol-induced deaths or 36,500 suicides in 2008 — according to U.S. National Vital Statistics Reports [Kochanek et al. 2011] — are not also considered epidemics. Furthermore, a portion of those other deaths likely involved persons with unrelieved pain who were not being adequately treated with opioids or other modalities, and this is certainly a public health threat worthy of attention.

Similarly, it is of interest that the 16,500+ annual deaths in the U.S. attributed to NSAID-related gastrointestinal adverse events, estimated more than a decade ago, were never categorized as an epidemic [Wolfe et al. 1999]. Furthermore, that number included only deaths associated with NSAID prescriptions for rheumatoid arthritis and osteoarthritis; it did not take into account deaths from OTC NSAID products, and cardiotoxic influences of NSAIDs on mortality were not fully recognized at that

time.

Of course, an obvious question also must be asked: Why is chronic pain in America not considered and portrayed as an epidemic? Certainly, even if the estimated 116 million adults with chronic pain, noted above, is somewhat of an overestimate, this is still a problem of staggering proportions and a major threat to public health and well-being.

Unintended Consequences & Opportunities for Change

Certainly, government agencies, like CDC, have a mission and obligation to warn the American populace of threats to public health, while at the same time promoting behaviors and treatments that promote individual and public health. As discussed throughout this paper, consideration should be given to whether actions resulting from those warnings might have unintended consequences that also may be detrimental to the health and well-being of Americans.

In Washington State, for example, which has instituted stricter rules governing opioid prescribing, there are reports of patients being unduly denied access to these medications and a consequent upsurge of heroin use and associated overdose deaths [Whitney 2011]. While this policy appears, on the surface, to be well-intentioned, a recent survey of Community Health Clinics in the state conducted by the American Pain Foundation, found that 70% of respondents indicated that they do not treat patients with chronic pain [APF 2011].

In another survey, 29% of primary care physicians and 16% of pain specialists reported that that they prescribe opioid analgesics less often than they think appropriate because of concerns about regulatory repercussions [Breuer et al. 2010].

A very recent survey of oncologists found that two of the greatest barriers in the management of cancer pain were (a) patients fears about taking opioids due to negative perceptions of the drugs and (b) practitioner concerns about excessive regulation of opioids [Breuer et al. 2011].

Undertreated or untreated pain, itself, carries risks of rising death rates. With a purported 116 million adult Americans afflicted with chronic pain it is important to consider the impact of potentially unrelieved pain on mortality. One study found that, even after adjusting for various confounding sociodemographic factors and effects of long-term illness, patients with severe chronic pain had a 49% greater risk of death compared with all-cause mortality in the general population and a 68% greater risk of death compared with all cardiovascular-disease-related deaths [Torrance et al. 2010].

While it cannot be said that appropriate prescribing of opioid analgesics would eliminate pain-related mortality, in balance, it is worth speculating that denial of access to these essential pain relievers might

contribute to death rates far greater than the 14,800 overdose deaths in which opioids were involved to some degree.

Another concern for person with chronic pain is suicide, which, as noted above, far outnumber opioid overdose deaths and might be considered an epidemic. Attempted and successful suicide rates have escalated dramatically in the U.S. [SAMHSA 2011] and, according to one report, risk of death by suicide is at least doubled in patients with chronic pain [Tang and Crane 2006]. In this study, the lifetime prevalence of suicide attempts was between 5% and 14% in individuals with chronic pain, and persons with more than one type of chronic pain are almost 3 times more likely to attempt suicide than persons without such pain.

When considering the extremely high prevalence of chronic pain in America, pain-related suicides could become a significant cause of mortality. And, while opioid analgesics providing more adequate pain relief may not be a complete solution, sizeable reductions in prescribing could have serious repercussions.

It also must be considered that alternative analgesic medications carry significant risks of morbidity and mortality, which may be much greater than for opioids in some populations [Leavitt 2010]. For example, as noted above, NSAIDs have significant risks of gastrointestinal and cardiac complications, while acetaminophen is a significant cause of liver failure in the U.S. A shift from opioid analgesics to these other agents for moderate to severe pain of any origin could have significantly negative repercussions on public health and mortality.

A preponderance of articles on opioid analgesics these days in medical journals, as well as presentations at pain conferences, focus on risks and harms of these drugs and how to cautiously screen and monitor patients. While such education is important, the unbalanced emphasis on negative perspectives also promotes an increasing cynicism and "opiophobia" among practitioners, which denies the relatively high level of safety of these agents when properly prescribed and used.

A more balanced perspective would devote equal space/time to discussions of how opioid analgesics are or can be essential for improved functionality and quality of life; along with which patients, with what pain conditions, could benefit most.

For many patients, opioids are but a temporary measure; however, for some, these drugs may be a vital and relatively safe lifelong therapy for maintaining a more normal, comfortable existence; much like insulin, antihypertensives, antidepressants, or other medications are necessary in some patients. Rarely, if ever, would patients choose opioids (or any medication) over nonpharmacologic approaches, if the latter were readily accessible, affordable, and could provide comparable, lasting relief from pain and suffering.

Considerations for Future Action

As described above, there are currently many challenges associated with achieving a balanced dialog concerning opioid analgesics for chronic noncancer pain; from clarity of definitions, to uses of language, to how relevant data are best gathered, interpreted, and communicated. This is complicated by the fact that there is often poor quality or inadequate information on both sides of the dialog, whether considering risks/harms or benefits of opioid analgesics.

PCF members would are interested in working with CDC — exerting a leadership position in concert with other relevant government agencies — to consider the following:

- Rapidly pursue the development and dissemination of practical and scientifically accurate forensic case definitions of opioid-attributed overdoses and deaths to be used consistently nationwide by medical examiners and coroners, as well as by epidemiologists and researchers.

- Conduct a review of existing assessment and treatment guidelines intended for use by practitioners, focusing on evidence base, utility, outcomes and implementation barriers.

- Convene a multidisciplinary and independent panel of experts who would be charged with performing and reporting on the following tasks:
    - Assess current communications coming from government sources in terms of whether balance is achieved in the accurate, unbiased presentation of risks and benefits of opioid analgesia for chronic noncancer pain.
    - Reassess available epidemiological data, research studies, and treatment guidelines relating to 1) the prevalence of the various chronic pain conditions, 2) opioid analgesic prescribing patterns and practices, 3) barriers to implementation of assessment or treatment guidelines, and 4) associated adverse events or problems from perspectives of consistency of data, clarity of definitions, and quality of evidence.
    - Identify areas where good-quality data are lacking, where alternative explanations for current trends/problems might exist, and areas for necessary further investigation and evidence gathering.

- Based on the above findings, facilitate the development of uniform definitions and classification schemes to be used consistently by all agencies and researchers that collect data on opioid analgesic use, misuse, and related adverse events.

- Identify where there is a potential for unintended negative consequences due to gaps in data or knowledge, potential misunderstandings of research evidence, the miscommunication of information to the public, and current legislative or agency actions expected to control opioid-related problems.

- Develop recommendations for how, based on current best evidence, appropriately balanced messages regarding opioid analgesics for chronic noncancer pain can and should be conveyed to the healthcare community and the public.

- Develop for implementation by all concerned government agencies a Manual of Style — a guide for authors/editors — that encourages the use of technically correct, unbiased, and rhetorically neutral language in balanced communications pertaining to substance-use problems, opioid analgesic therapy, and issues associated with the treatment of chronic pain.

As noted at the outset, the goal of a balanced dialog — based on unbiased information and high quality evidence — is to help safeguard the public health while assuring that all persons suffering chronic pain will have medically appropriate access to vital analgesic medications that help them to live more functional and better lives.

Resolving the conundrum

Reaching an acceptable solution to this intricate and difficult problem requires that society set a goal of achieving balance in public policy. Such a goal recognizes, as federal statutes do, that government has a dual responsibility to make prescription opioids available for all who need them to treat pain, while reducing illicit demand and restricting access to those who would divert or abuse them. This principle of balance is embodied in the WHO's Single Convention on Narcotic Drugs, to which the US is a signatory. (ref) Keeping the need for balanced policy foremost in efforts to address these two serious public health problems is vital to developing solutions that enable us to treat each problem without worsening the other.

General References (Regulatory References follow)

Regulatory References

Fla. Stat. Ann. §§ 456.037, 458.3265, 458.327, 458.331, 459.013, 459.0137, and 459.015 (West 2011)

Fla. Admin. Code Ann. r. 64B-4.005, 64B-4.006, 64B8-9.0131, 64B-9.0132, 64B26-14.0051 and 64B-14.0052 (2011)

Ohio Rev. Code Ann § 4731.054 (West 2011)

Ohio Admin. Code 4731:29-01 (2011)

La. Rev. Stat. Ann. §§ 40:971.2, 40:2006, 40:2198.11, 40:2198.12 and 40:2198.13 (2011)

La. Admin. Code tit. 48, §§ 7801 through 7861 (2011)

Tenn. Code. Ann. §§63-1-302 through 63-1-311 (West 2011)

The final version of implementing regulations is currently under consideration – the proposed citation is:

Tenn. Comp. R. & Regs. §§ 1200-34-01.01 to .10 (2011)

Tex. Occ. Code Ann. §§ 168.001, 168.002, 168.051, 168.052, 167.053, 168.101, 168.102, 168.151, 168.152, 168.201, 168.202 (Vernon 2011)

22 Tex. Admin. Code §§ 195.1 through 195.4 (2011)